



United States Department of Agriculture (USDA)
 Animal and Plant Health Inspection Service (APHIS)
 Veterinary Services (VS)
 National Import Export Services (NIES)

NIES AT ITS BEST

Animal Products Permitting and Negotiation Services (APPNS)

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Our Mission

- Safeguard the health of domestic livestock and poultry by inspecting and quarantining animals and animal products to mitigate animal disease risk through risk assessments and sound science
- Facilitate trade, promote safe movement, negotiate science-based import/export requirements, and collaborate with other agencies and departments to remove technical barriers to trade
- Serve as the preeminent resource for safeguarding the nation's food supply from agricultural select agents and toxins
- Cooperate and collaborate with international animal health standard setting organizations to develop science-based health measures for safe trade
- Utilize science-based performance measures and a focus on consistent, standard practices carried out by a responsive workforce

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Animal Product

Any material derived from the body of an animal. Examples are fat, meat, skin, organs, blood, milk, eggs, and lesser known products such as rennet, gelatin and rendered animal meals.



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Do I need a permit?

USDA e-Authentication

ATTENTION ALL CUSTOMERS!

In the very near future, NIES will be retiring the ePermits system in favor of CARPOL, a newer, more customer friendly system. However, to experience all the benefits and features of the new system, we strongly recommend that you become e-Authenticated as early as possible. The new system requires customers to be a Level-2 subscriber in order to retrieve even the simplest of items, such as finished permits. **Please don't delay; become eAuthenticated today!**

USDA agencies use the e-Authentication system to provide customers accounts that will allow them to access USDA Web applications and services via the Internet. This access includes applications to submit forms electronically, complete surveys online, and check USDA account status.

Please note that USDA will only grant e-Authentication accounts to individuals. USDA does not have the mechanism to issue accounts to businesses, corporations, or other entities.

To apply for a USDA e-Authentication account, please visit our website at

www.eauth.usda.gov

NIES Animal Products Permitting and Negotiation Services issues permits for animal origin material. However, there are certain products that do not require a permit from our office. Please see the list below to see a list of materials that **do not require a USDA import permit, but will be reviewed at the port of entry.** You can also find this information at <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information>

[1100](#) Human Pharmaceuticals and Human Vaccines Containing Animal Components

[1101](#) Non-Human Primate Material (excluding cell cultures)

[1102](#) Feline and Canine Material

[1103](#) Live Laboratory Mammals and Their Material (for research purposes)

[1104](#) Amphibians, Fish, Reptiles, Shellfish and Aquatic Species (includes venom) Revised June 2014

[1105](#) Chemically Synthesized Materials

[1107](#) Guidelines for Importation of Lactose and Lactose Derivatives

[1110](#) Microbially Produced Materials

[1114](#) Recombinant Microbes and Their Products

[1116](#) Non-Pathogenic Microorganisms (and their extracts)

[1119](#) PET CHEWS/TREATS made of ANTLERS or RAWHIDE

[1120](#) Cell Cultures/Lines, Recombinant Cell Cultures/Lines, and Their Products (for in vitro use)

[1121](#) Test Kits

[1122](#) Vitamins and Minerals

[1123](#) Histopathological Fixed Slides

HOT TOPICS

VS Assists in Import of Canine Cancer Drug for Personal Use by Pet Owners

Masivet is a cancer drug, which contains porcine liver and is used to treat mast cell tumors in dogs. The drug is approved in Europe, but not the United States. When we learned that this drug was being imported by veterinarians/veterinary clinics without an import permit, and it was detained at various ports of entry by Customs and Border Protection (CBP) Ag Specialists, we quickly determined that the treatment did not present an animal health risk, facilitated release of the detained shipments, and worked extensively with owners and patient advocates to ensure their pets received this vital cancer treatment. The appreciation for addressing this issue in a timely manner was expressed by emails from appreciative dog owners once they received the drug.

We then compiled and issued a special import permit (VS Form 16-6) to facilitate the import of this vital drug. Each shipment was required to be accompanied by an original, signed statement from the exporter or manufacturer. Unfortunately, personnel changes at the exporting company led to Masivet shipments arriving without the required manufacturer's documentation, which resulted in detained shipments at the port of entry. NIES again facilitated release of the detained shipments and worked extensively with involved stakeholders to arrive at, and communicate, a plan to avoid future documentation problems.

To assist with facilitating the import of this vital cancer treatment for U.S. pets, NIES also issued a CBP *Import Alert*, to provide a process for CBP to facilitate release and communication regarding Masivet shipments. This alert gave CBP information the flexibility to accept permit modifications such as copies instead of an original document, as long as the permit-required statement is included on the invoice, signed by the exporter, and accompanies each shipment.

NIES is hopeful this modification of the permit and original documentation requirements will avoid future detained shipments and delay in providing this vital cancer drug to canine patients.



DEREGULATION OF FDA APPROVED HUMAN PHARMACEUTICALS & VACCINES

Human and veterinary drugs and pharmaceuticals often contain animal-derived ingredients. APHIS has authority to regulate the import of animal-derived products that present a risk of introducing foreign animal diseases into the United States. APHIS coordinates with the U.S. Food and Drug Administration (FDA)—the agency responsible for regulating human drugs and vaccines, as well as veterinary drugs—to ensure that such materials don't present an animal health risk. APHIS and FDA have determined that FDA-approved human and veterinary pharmaceuticals, and most human vaccines in final dosage form, present a negligible risk for introducing foreign animal disease into the United States. Thus, these commodities may enter the United States without APHIS restrictions.

With this new policy, a USDA APHIS VS import permit (VS Form 16-6) will no longer be required for the importation of human pharmaceuticals and vaccines, or veterinary pharmaceuticals approved by the Food and Drug Administration (FDA). This new policy will impact human and veterinary pharmaceutical companies. If you have further questions about animal products and their eligibility for importation into the United States or their certification requirements, please contact NIES at (301) 851-3300, option 1, or via email at AskNIES.Products@aphis.usda.gov.

PARTICIPATION AT THE CONECT BIOTECH SEMINAR

On March 14, NIES virtually joined the Coalition of New England Companies for Trade (CONECT) Import Biotech Seminar, to provide a 20 minute presentation on USDA APHIS activities, import policies and regulations, and veterinary import permit application instructions. CONECT is a non-profit business association serving over 1,200 members representing more than 300 companies and organizations, involved in international trade or transportation. Approximately 50-75 importers, brokers, and government agency representatives from the southern New England area attended the Import Biotech seminar. After the presentation, NIES answered several questions about the import of gelatin and the use of the new *Guideline 1100: Human Pharmaceuticals and Human Vaccines Containing Animal Components*.

African Delegation



On February 8, NIES spoke with visiting Cochran Fellows from Africa. We described the role and functions of the Animal Products

Permitting and Negotiation Services in the import and export of animal products, and presented an overview of our engagement with the World Organization for Animal Health (OIE) – including its history, its objectives and its mandates. Following the presentations, there was good discussion with many questions asked by the Fellows.

Renewable Energy Group

On February 9, NIES had the opportunity to host a small and informative meeting with Renewable Energy Group.

Their company's focus is to utilize, cleaner, lower carbon intensity products, such as biodiesel fuel derived from animal fats or used cooking oil, through innovation and hard work. We discussed our policies and regulations as it relates to the importation and intended use of these materials and ways that we could work together to provide better service.

Email Communication Tools

For **permit applications or status requests** related to animal products or by-products, please contact us via email at animalproducts.application@aphis.usda.gov. Remember to include permit or application numbers, for faster assistance.

For **questions** related to animal products or by products, please email us at asknies.products@aphis.usda.gov. We will respond within 48 business hours.

If email is not convenient, we welcome your phone call at 301-851-3300, Option 1.



Application Fees to import an animal or animal byproduct into the United States are as follows:

Application	Fee
New Application	\$150
Renewal Application	\$97
On-Hold Applications	\$565
Amendments	\$75
Fetal Bovine Permits	\$512

Payment for services rendered is considered a processing fee (non-refundable) and does not guarantee permit approval or shipment release

Work Around the World

Gaining Market Access for U.S. Agricultural Commodities

Fiji:

December 1, 2016 - In response to our letter to Fiji requesting lifting of Bovine Spongiform Encephalopathy (BSE) related import restrictions on U.S. origin ruminant meat, meat products, and dairy products, APHIS received a letter from the Biosecurity Authority of Fiji officially recognizing the United States' negligible risk status for BSE. The United States does not currently export either live cattle or beef to Fiji, but Fiji stated their willingness to begin discussions to negotiate requirements and health certificates to facilitate future exports. U.S. agricultural exports to Fiji totaled \$9.7 million in 2015.

Belarus:

December 1, 2016 - Belarus issued a decree lifting avian influenza related restrictions on imports from Missouri, its last AI-related trade ban on imports from the United States. The ban was implemented on March 8, 2015 and initially prohibited the import of poultry and poultry products as well as equipment used for transportation, maintenance, slaughtering, and cutting of poultry from the entire United States. It was later narrowed to include only certain States and, except for Missouri, these prohibitions were removed on October 5, 2016. When the HPAI-related bans were lifted on other States, the ban on Missouri remained due to the detection of low pathogenicity avian influenza (LPAI) in a commercial flock in the State. The last restriction was removed after APHIS met with Belarussian authorities and provided additional information related to AI eradication. The estimated value of this trade accomplishment is \$2 million per year.

European Union:

December 3, 2016 - To retain market access for gelatin and/or collagen, APHIS completed transition to new certificates required by the European Union for consignments of materials (e.g. hides or bone chips) intended for the production of gelatin and/or collagen for human consumption in the European Union (EU). The previous versions of the certificates will no longer be accepted by the EU. Implementation of the new certificates required APHIS to develop new inspection criteria, and to educate industry and the Veterinary Services field offices (the offices that endorse the certificates) on the new certificates and related criteria.

Saudi Arabia:

December 5, 2016 - The Saudi Commercial Attaché informed APHIS that the Saudi Food and Drug Authority (SFDA) removed the temporary ban on the imports of beef and beef products from the United States. Moreover, SFDA has designated the USDA as an approved monitoring organization and the regulatory authority for this matter. SFDA has been authorized to accredit beef and beef product exporting companies which been approved by the USDA and are under its supervision.

Myanmar:

December 2, 2016 - APHIS received confirmation that Myanmar lifted previously imposed restrictions on U.S. poultry and poultry products, originally implemented due to avian influenza. Poultry meat and meat products from affected States produced on or after December 2, 2016, are eligible for export to Myanmar.

Work Around the World

(Continued)

India:

December 15, 2016 - India's Department of Animal Husbandry, Dairying, and Fisheries (DADF) formally accepted a certificate proposed by VS for the export of bovine gelatin. Previously, trade of this product was impeded by DADF's requirements for the United States to provide certification attesting to a U.S. Controlled Risk status for BSE and restrictions on the use of specified risk materials based on this status. Discussions during the November 2016 U.S.–India Bilateral in New Delhi, India, paved the way for DADF recognition of U.S. Negligible Risk Status for BSE and acceptable certification language to facilitate the export of bovine gelatin. Exports of U.S. gelatin to India totaled \$2.3 million in FY 2016.

Philippines:

December 12-16, 2016 - APHIS hosted the Philippine Bureau of Animal Industry (BAI) delegation for the animal health portion of a systems audit of meat exports, a market valued at \$190.7 million. The visit was a cooperative venture between industry and USDA. It included presentations by USA Poultry and Egg Export Council, National Cattleman's Beef Association, National Pork Council, Food Safety Inspection Service, APHIS Plant Protection and Quarantine (Quarantine Policy Analysis and Support) and APHIS Veterinary Services. Tours were provided of an FSIS I-House and the National Veterinary Services Laboratories in Ames, Iowa. The goal of the audit was to maintain market access for U.S. meat/meat products to the Philippines. The delegates seemed very pleased with the material presented and tours provided, and appreciated the efforts of USDA to deliver high quality information and give immediate responses to questions.

Brazil:

December 7, 2016 - After finalization of a letterhead certificate in August 2016, the United States and Brazil reached an agreement on labeling requirements for beef for human consumption. This agreement re-opened the Brazilian market for U.S. beef and beef products; a market closed for the last 13 years. On December 15, the Food Safety Inspection Service (FSIS) updated its Export Library for Brazil, and U.S. beef and beef product exports are expected to resume in early 2017. As of today, three plants are registered/eligible to export to Brazil. FSIS has sent a letter to Brazil requesting to register 24 more facilities. U.S. beef and beef product exports to Brazil could reach \$5-10 million annually.

New Zealand:

December 23, 2016 - New Zealand's Ministry of Primary Industries (MPI) notified APHIS of their acceptance of the model veterinary certificate for U.S. cooked turkey meat. This notification is the result of 2 years of engagement between USDA (APHIS, FAS, and FSIS) and MPI following New Zealand's 2015 implementation of new import health standards for turkey meat. Access to New Zealand has been a high priority for U.S. industry as New Zealand does not have large commercial production of turkeys or turkey products.

Work Around the World

(Continued)

Korea:

On January 6, 2017 - Korea accepted a USDA proposal to allow the export of U.S. table eggs for human consumption into Korea. This market has been closed since the onset of the 2014 outbreak of HPAI in the United States. Though the animal disease attestations required by Korea are certified by the USDA's Agricultural Marketing Service (AMS), APHIS played a critical role during negotiations by providing accurate disease-free statements. Under normal market conditions, the U.S. supplies one-quarter to one-third of Korea's egg and egg product imports. With the current shortages Korea is experiencing due to their HPAI outbreak—which decimated more than one-quarter of Korea's poultry stock—U.S. exports to Korea are expected to increase substantially. In March 2017, Korean officials will be performing a site-visit to U.S. egg packaging and egg processing facilities to review sanitary procedures to maintain market access.

Vietnam:

January 9, 2017 - Vietnam's Department of Animal Health (DAH) approved proposed alternative language to update the U.S. BSE negligible risk classification status as recognized by the World Organisation for Animal Health (OIE). These updates revised an export health certificate used to export bovine-origin bone-derived gelatin and the current live cattle protocol used to export live cattle to Vietnam. The revisions enabled APHIS to maintain current market access for live cattle and bone-derived gelatin of bovine origin.

Taiwan:

January 4, 2017 - Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) accepted APHIS-proposed certification language for U.S. origin unprocessed egg products exported to Taiwan. While FSIS is the certifying authority for egg products exported to Taiwan, APHIS served as lead negotiator for these modifications. A 3 month transition period will be implemented upon confirmation of acceptance of the model export health certificate. These certification updates are crucial to continue trade in the event of an avian influenza outbreak from unaffected regions of the U.S.

Middle East:

NIES, in conjunction with International Services International Trade and Regulatory Capacity Building staff, conducted a mission to Saudi Arabia, Qatar, Kuwait, and Morocco in January 2017. The purpose of the visit was to conduct meetings with upper level ministerial counterparts to strengthen bilateral relationships with trading partners and advance initiatives to open, retain, and/or expand market access for U.S. poultry and poultry products. As part of the meetings, Dr. John Clifford, NIES Chief Trade Advisor, provided an overview of the surveillance findings of the 2015 HPAI outbreak, which served as a segue to discussions regarding regionalization and the process for implementing and lifting avian influenza restrictions.

Work Around the World

(Continued)

Taiwan:

Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) accepted APHIS proposed health certificates for feathers. This includes one certificate for feathers derived from States free of HPAI and/or Newcastle disease, and a second certificate for feathers from States affected by HPAI and/or Newcastle disease. Beginning February 7, BAPHIQ established a 60 day transition phase to the new certificate. Both the current and new certificates will be accepted during the transition period. Once the transition period ends on April 7, 2017, only the new certificate will be accepted.

Costa Rica:

February 2, 2017 - Costa Rica agreed to amend a statement for the certification of heat treated pet food to Costa Rica, to allow for treatments other than heating that would destroy viral and bacterial pathogens transmissible through the product. This amendment opens the market for high pressure processed pet foods that were not previously covered under the old certification statements.

Peru:

In discussion with NIES and International Services, Peru agreed on a more streamlined process for the registration approval by Peru of animal product and by-product processing facilities inspected by APHIS and wishing to export to Peru. This has decreased the approval time from several months to one month or less.